Department of Veterans Affairs **VHA DIRECTIVE 2002-070**
Veterans Health Administration
Washington, DC 20420 **November 13, 2002**

ENSURING CORRECT SURGERY

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides specific information on what steps must be taken to ensure that the indicated surgical procedure(s) is performed on the correct patient, at the correct site, and if applicable with the correct implant. ***NOTE:*** *Correct site includes the correct side (i.e., left or right) and the correct precise anatomical location, e.g., specific vertebral body or finger.*

2. BACKGROUND

a. Wrong site, wrong patient, and wrong implant procedures are relatively uncommon adverse events in health care but are often devastating when they occur. To address the fact that VHA does not have documented standardized guidance on how facilities should best focus their efforts to prevent these adverse events, VHA established the VHA Working Group on Ensuring Correct Site and Correct Patient Procedures and pilot tested a set of preventive steps at ten Department of Veterans Affairs (VA) medical centers during the summer of 2002. The ten pilot test sites reported that implementing the steps was not an unduly arduous process, and in a post-pilot evaluation a large majority of operating room personnel responded that the steps were worthwhile, sensible, and likely to help prevent incorrect surgeries. The actions described in Paragraph 4 and Attachments A, B, and C are based on the steps developed by the Working Group and tested by the pilot test sites.

b. Attachment A covers the time period from days to about an hour before a typical surgery. During this time the informed consent process must be completed (from 30 days prior to the same day as surgery), and the surgical site must be marked (usually the same day as the surgery). Attachment B covers the time period just prior to bringing the patient into the Operating Room. Attachment C covers the time period in the Operating Room before surgery begins. One way to achieve the required documenting of completion of these procedures is to add them to the facility's existing checklist of actions and steps that must be completed preoperatively.

c. To facilitate the development of local procedures and policy documents, Attachment D contains a sample facility policy. This document incorporates the required steps and is based on a policy developed during the pilot test phase.

d. Appendix E provides additional strategies, techniques, and tools that are not required by this Directive, but which merit consideration in the development and implementation of facility policies and procedures.

3. POLICY: It is VHA policy that at VHA facilities where surgery is performed specific steps must be implemented in order to reduce the likelihood of incorrect surgeries (See Att. A, Att. B, and Att. C).

THIS VHA DIRECTIVE EXPIRES NOVEMBER 30, 2007

4. ACTION: The Facility Director is responsible, no later than January 1, 2003, for ensuring that:

a. Except in cases of medical emergencies, or those rare situations where certain steps are impossible to complete, if a step required by this Directive has not been performed, the next step must be delayed until the previous step has been completed; i.e., steps in Attachment C cannot start until the steps in Attachment B are completed; and those steps in Attachment B cannot start until the steps in Attachment A are completed. ***NOTE:*** *In the rare cases where the steps are not all followed, the justification for the deviation(s) must be documented.*

b. A facility policy document is put into effect that describes the required specific steps (See Att. A, Att. B, and Att. C) that must be implemented in order to reduce the likelihood of incorrect surgeries;

c. The execution of these steps is documented in the patient's record (See Att. A, Att. B, and Att. C); and

d. The implementation of the steps and conformance to the facility's policy document(s) is monitored for compliance.

5. REFERENCES

a. American Academy of Orthopedic Surgeons: Academy statement on wrong-site surgery. Accessed 9/6/2002. Available at: www.aaos.org/wordhtml/2000news/c9-16.htm.

b. Joint Commission on the Accreditation of Healthcare Organizations. 2003 Patient Safety Goals. Accessed 9/6/2002. Available at: www.jcaho.org/news+room/press+kits/npsg.htm

c. Joint Commission on the Accreditation of Healthcare Organizations. Simple Steps by Patients, Health Care Practitioners Can Prevent Surgical Mistakes. Accessed 9/6/2002. Available at: www.jcaho.org/news+room/press+kits/wrong+site+surgery.htm

d. Joint Commission on the Accreditation of Healthcare Organizations. Sentinel Event Alert, Issue 24 - December 5, 2001, A follow-up review of wrong site surgery. Accessed 9/6/2002. Available at: www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_24.htm

e. Association of Perioperative Registered Nurses (AORN). AORN Position Statement on Correct Site Surgery. Accessed 9/6/2002. Available at: www.aorn.org/about/positions/correctsite.htm

f. American Academy of Ophthalmology: Eliminating Wrong Site Surgery, Patient Safety Bulletin Number 1. Accessed 9/6/2002. Available at: www.aao.org/aao/education/library/safety.cfm

g. Minimizing Wrong IOL Placement. Patient Safety Bulletin Number 2. Accessed 9/6/2002. Available at: www.aao.org/aao/education/library/safety_iol.cfm

h. New York State Department of Health Pre-Operative Panel Final Report. Accessed 9/6/2002. Available at: www.health.state.ny.us/nysdoh/commish/2001/preopletter.htm

i. VHA Incorporated. VHA Promotes Surgical Site Verification Program. Program introduces "seven absolutes" to reduce surgical errors. Accessed 9/6/2002. Available at: www.vha.com/pagebuilder.asp?url=/publicreleases/020114.asp

j. Evidence Report/Technology Assessment, No. 43. Making Health Care Safer: A Critical Analysis of Patient Safety Practices, Robert M. Wachter. Accessed 9/6/2002. Available at: www.ahcpr.gov/clinic/ptsafety/

(1) Subchapter 43.2. Strategies to Avoid Wrong-Site Surgery, Heidi Wald, Kaveh G. Shojania. Accessed 9/6/2002. Available at: www.ahcpr.gov/clinic/ptsafety/chap43b.htm

(2) Chapter 48. Procedures For Obtaining Informed Consent, Laura T. Pizzi, Neil I. Goldfarb, David B. Nash. Accessed 9/6/2002. Available at: www.ahcpr.gov/clinic/ptsafety/chap48.htm

k. Risk Management Foundation of the Harvard Medical Institutions. Did Wrong-Site Surgery Remedy Work? Accessed 9/6/2002. Available at: www.rmf.harvard.edu/publications/resource/feb1999news/article2/index.html

l. Meinberg, E, Stern, PJ, "Incidence of Wrong Site Surgery among Hand Surgeons," Poster presentation a t the American Academy of Orthopedic Surgeons Annual Meeting in Dallas, TX, February 13-17, 2002. Available at: www.aaos.org/wordhtml/anmt2002/poster/p375.htm

m. VHA Handbook 1004.1. Available at: www.va.gov/publ/direc/health/handbook/1004-1hk.pdf

6. FOLLOW-UP RESPONSIBILITIES: The VHA National Center for Patient Safety (10X) and the Office of Patient Care Services (111B) share responsibility for the development and contents of this Directive. Questions regarding this directive may be addressed to the National Center for Patient Safety at (734) 930-5920.

7. RESCISSION: None. This VHA Directive expires November 30, 2007.

Robert H. Roswell, M.D.
Under Secretary for Health

Attachments

DISTRIBUTION: CO: E-mailed 11/14/02
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ATTACHMENT A

MINIMUM PRE-OPERATIVE PROCEDURES
(Days to approximately 1 hour before surgery)

1. The consent form to be signed by the patient (or the individual legally entitled to consent on behalf of the patient) pre-operatively must state the procedure site, including laterality if applicable, and the name of, and reason for, the procedure to be performed.

ACTION: The medical center Director, or designee, is responsible for ensuring that facility consent forms facilitate providing the required information on the:

a. Site of the procedure,

b. Laterality of the procedure,

c. Name of the procedure, and

d. Reason for the procedure.

Rationale: *This is to ensure that the patient understands where the surgeon intends to operate, as well as what procedure is to be performed and why. To improve safety, it gives the patient or their representative the opportunity to identify a mistake at a time that is removed from when the surgery is imminent when there may be many distractions that prevent attention to what is on the consent form.*

NOTE: *In order to consent, the patient must possess a decision-making capacity, be fully informed, and participate voluntarily. Decision-making capacity is defined, in VHA Handbook 1004.1 - Informed Consent Procedures, as "the ability to understand and appreciate the nature and consequences of health care treatment decisions." Decision-making capacity may be precluded by a disease state or heavy sedation. It needs to be noted that sedation by itself does not prevent the patient from possessing a decision-making capacity; the patient's decision-making capacity must be determined based on the facts of the particular circumstance. For example, a patient who is extremely anxious may actually be better able to provide informed consent once an anxiolytic drug is given. Similarly, a patient in pain should not be denied the necessary pain medications. VHA Handbook 1004.1 (http://vaww.va.gov/publ/direc/health/handbook/1004-1hk.pdf) also states that the patient's written consent is valid for 30 days after it is given, contains guidance on when signature consent can be given by a surrogate, and addresses many other pertinent issues.*

2. The medical center Director, or designee, is responsible for putting procedures and methods in place that specify pre-operative marking of the operative site by a physician member of the operating team (surgeon, resident, fellow), or other privileged provider, performing the invasive procedure. The physician, or other privileged provider, who marks the site must be a member of the operating team assigned to be present in the operating room during the procedure. The purpose for marking the site is to clearly indicate the procedure site and needs to be done with the involvement of the patient. Indicating the site with appropriate precision needs to be the

primary consideration when placing the mark. For emergencies these procedures need to be applied to the extent possible, and facilities must have policies and procedures in place that specify when marking is not required.

ACTION: The medical center Director, or designee, is responsible for specifying exactly how physicians or other privileged providers are to mark operative sites and document that the marking process has been completed: a typical standard practice is to use an appropriate marking pen and to mark the site with the physician's initials or an "X." The site needs to be marked so that it is unambiguous; for example, for surgery on a finger, the finger is to be marked rather than the palm or back of the hand. Whenever possible the mark needs to be placed so that it will be visible in the operative field after of the site is prepared and draped. Always use ink that will withstand pre-surgical preparation of the operative site. Do not use adhesive stickers to mark a site.

Rationale: *Marking the site makes clear where the surgery is to be performed. Having the surgeon or other designated member of the surgical team mark the site will help ensure that the mark is put at the correct site. Although patients need to corroborate the site as the surgeon marks it, patients are not to mark the site.*

3. To prevent confusion non-operative sites must not be marked, unless required for another aspect of care.

ACTION: The medical center Director, or designee, is responsible for ensuring that local policy explicitly states that the non-operative sites must not be marked, unless required for another aspect of care.

Rationale: *When non-operative sites are marked, these marks may cause confusion and have the opposite of the intended effect. For example, "X" may signify "operate here" to one person and "don't operate here" to another.*

ATTACHMENT B

MINIMUM PROCEDURES BEFORE THE PATIENT ENTERS THE OPERATING ROOM

(Usually an hour or less before surgery)

The patient must be asked by staff to verbally state (not confirm): (a) the patient's name, (b) full social security number or birth date, and (c) the location on the patient's body at which the patient understands the procedure will take place. These responses must be checked by staff against the completed consent form, marked site, and patient identification band, as applicable. This must occur in the immediate pre-operating room (OR) environment, for example in the hallway adjacent to the OR, etc., but not in the patient's room. In general, this needs to be done prior to sedation of the patient, but this may not be possible in some cases. Whenever possible in cases where the patient cannot act on their own behalf, the individual who provided informed consent needs to be asked to state the name of the patient and the site to be operated on. For emergencies these procedures need to be applied to the extent possible.

ACTION: The medical center Director, or designee, is responsible for establishing which personnel or job position(s) are to be assigned the task of asking the patient to state the patient's identity and what the patient understands to be the site of the upcoming procedure. In addition, it must be established how the patient's answers are to be documented and checked against local documents, including the consent form.

Rationale: *Asking the patient to state rather than confirm their name helps prevent miscommunication and wrong-patient procedures. Patients who are hard-of-hearing or distracted by illness or other temporary or permanent disability may say "yes" to a name that is not theirs, but it is very unlikely that they will misstate their name and birth date or social security number when asked. Asking the patient to state where the patient expects to be operated on is a final check prior to the provision of anesthesia, after which the patient will likely be unable to intervene on his or her own behalf. Verifying the information physically and temporally close to the place and time of the procedure helps prevent wrong patient procedures. Verifying the information in the patient's room would be less effective in reducing the vulnerability to an adverse outcome.*

ATTACHMENT C

MINIMUM OPERATING ROOM PROCEDURES
(Minutes to seconds before surgery)

1. The medical center Director, or designee, is responsible for ensuring that procedures are in place that require verification of the correct patient, the correct procedure, the correct site, and the correct implant (where applicable) by operating room personnel in the Operating Room (OR) prior to the start of the procedure, and at a time when the patient and operating room personnel are present in the operating room. In most or many cases the patient will be under sedation or unconscious as this verification occurs.

ACTION: The medical center Director, or designee, is responsible for establishing a specific procedure by which members of the OR team verify their agreement as to the intended surgery prior to the start of the procedure. A standard method is a "time out," during which a designated member of the OR team states the name of the patient, the procedure to be performed, the location of the site (including laterality if applicable), and the specifications of the implant to be used (if applicable). After the statement, other members of the team verbally state that they concur with this information before the procedure begins. At minimum, this process must include the surgeon, the circulating nurse, and the anesthesia provider. Successful completion of this process must be documented.

Rationale: *This makes sure everyone "is on the same page."*

2. The medical center Director, or designee, is responsible for ensuring that procedures are in place requiring two members of the operating team to verify, prior to the start of a procedure, that when imaging data are used to determine or confirm the operative site, the relevant images for the correct patient are available, properly labeled, and properly presented.

ACTION: For procedures during which physicians will refer to pre-existing images, the medical center Director, or designee, is responsible for ensuring that a method for documenting that two members of the OR team have confirmed that the images are available, correct, properly labeled, and properly presented.

Rationale: *Errors in determining appropriate site due to lack of availability or improper labeling of images is a real vulnerability and methods to mitigate this vulnerability need to be in place.*

ATTACHMENT D

SAMPLE POLICY DIRECTIVE

CORRECT-SITE SURGERY PROCEDURES

1. PURPOSE: This (Name) VA Medical Center Policy Directive establishes effective identification of the correct site, patient, and implant for a surgical or invasive procedure.

2. POLICY: It is Surgical Clinical Care Center policy establishes a procedure to eliminate the possibility of wrong-site, wrong-patient, or wrong implant surgical or invasive procedures.

3. ACTION

a. The physician must:

(1) Advise the patient or surrogate decision maker of proposed significant other of the required procedure and identify the body part directly involved. This information will be recorded in the patient's medical record.

(2) Review the following data after scheduling the patient for surgery and prior to the surgery:

(a) X-rays (and other imaging reports).

(b) Pre-procedure history and physical (H&P), and other clinically relevant material (i.e., consults, progress notes, laboratory values, etc.) in the patient's medical record.

b. The Optional Form (OF) 522, Request for Anesthesia and for Performance of Operations and Other Procedures, to be signed by the patient (or the individual legally entitled to consent on behalf of the patient) must state the procedure site, including laterality if applicable, and the name of and reason for the procedure to be performed. ***NOTE:*** *Abbreviations are not to be used; "right," "left," "both," etc., need to be written out.*

c. Prior to the patient entering the Operating Room (OR), a physician member of the patient's operating team (attending surgeon, resident, or fellow) must mark the correct site, side, and location of the procedure with an appropriate marker. This must be done after asking the competent patient to state the patient's full name, full social security number, and the location on the body where the patient understands the procedure will take place.

d. The site must be marked with the physician's initials, except in special cases where a smaller mark is desired (for example, near the eye).

e. The mark must be placed on the patient's body in consultation with the patient and after confirming the identity of the patient with the patient. In a patient that lacks decision-making capacity, when possible, the surgeon needs to ask the authorized surrogate to state the name of the patient and confirm the operative site and side. The surgeon then marks the correct site according to facility policy.

f. It is important that whenever possible the mark be placed so that it is visible in the operative field after the site is prepped and draped. In the case of multiple level surgeries, for example spine surgery, the levels that are to be operated on need to be written next to the mark.

g. To prevent confusion, non-operative sites or sides <u>are not to be marked</u>, unless required for another aspect of care. Mucous membranes are not to be marked. Patients scheduled for endoscopy do not have their site marked, but all other steps described in this Directive apply.

(1) Outpatients and Same Day Admittance patients are to have the site marked in the pre-care area prior to the procedure.

(2) Inpatients may have their site marked in their rooms. Alternatively, after transportation by the OR team they may have site marked prior to the procedure in the pre-care area.

(3) Intensive Care Unit patients, including Emergency Care Service patients, are to have the site marked in their respective units prior to patient transport to the OR for the procedure.

(4) In the event of a life-threatening emergency, the site need not be marked prior to transporting the patient to the OR; however, the surgical team must concur about the correct operative site in the OR prior to the initiation of surgery.

h. Immediately before the patient enters the OR, a physician, nurse, physician assistant or medical technician associated with the care of the patient must ask the patient to state the patient's full name, full social security number or birth date, and to identify the operative site. The responses must be checked against OF 522, the identification bans, and other documents. This validation must be documented on the Pre-operative Checklist prior to the patient's transfer to the OR; the staff member who performs this check must stay with the patient until the patient is brought into the OR.

i. Prior to the start of the procedure, two members of the OR team must verify and document any imaging data that is used to confirm that the site is correct, is properly labeled with the patient's name and the correct side of the anatomy, and properly presented or oriented (left or right and up and down).

j. As a final check ("time-out") prior to the start of the procedure, at a time when the patient and the operating team are present in the OR, the presence of the correct patient, the correct marked site, intended procedure, and the correct implant (where applicable) must be verbally confirmed by the members of the operating room team (at a minimum, the surgeon, circulating nurse, and anesthesia provider). The circulating nurse must document the completion of the "time-out."

NOTE: *Asking the patient to state rather than confirm the name helps prevent miscommunication and wrong-patient procedures. Patients who are hard-of-hearing, or distracted by illness or other temporary or permanent disability may say "yes" to a name that is not theirs, but it is unlikely that they will misstate their name and birth date, or social security number when asked. Asking the patient to provide this information just prior to entering the OR acts as a final check prior to the provision of anesthesia, after which they will be unable to intervene on their own behalf.*

k. Except in cases of medical emergencies, or those rare situations where certain steps are impossible to complete, if any required action is found not to have been accomplished, the procedure must be delayed until the discrepancy is corrected. ***NOTE:*** *In the emergency or rare cases where the steps are not all followed and the decision is made to allow the procedure to proceed, the justification for the deviation(s) must be documented.*

4. REFERENCES

a. Joint Commission on the Accreditation of Healthcare Organizations. 2003 Patient Safety Goals. Accessed 9/6/2002. Available at: www.jcaho.org/news+room/press+kits/npsg.htm

b. Joint Commission on the Accreditation of Healthcare Organizations. Sentinel Event Alert, Issue 24 - December 5, 2001, A follow-up review of wrong site surgery. Accessed 9/6/2002. Available at: www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_24.htm

c. Association of Perioperative Registered Nurses (AORN). AORN Position Statement on Correct Site Surgery. Accessed 9/6/2002. Available at: www.aorn.org/about/positions/correctsite.htm

d. Risk Management Foundation of the Harvard Medical Institutions. Did Wrong-Site Surgery Remedy Work? Accessed 9/6/2002. Available at: www.rmf.harvard.edu/publications/resource/feb1999news/article2/index.html

e. VHA Handbook 1004.1. Available at: www.va.gov/publ/direc/health/handbook/1004-1hk.pdf

f. VHA Directive 2002-070, Ensuring Corrective Surgery. Available at: www.va.gov/publ/direc/health/publications.asp

5. RESPONSIBLE OFFICE: The Director, Surgical Clinical Care Center, is responsible for the contents of this memorandum.

6. RECISSIONS: Procedure 123-456, subject: Wrong-Site Surgery/Procedures, dated October 2000, is rescinded. This (Name) VA Medical Center Directive expires April 30, 2004.

John A. Doe
Director, VA MC

ATTACHMENT E

ADDITIONAL STRATEGIES, TECHNIQUES, AND TOOLS TO HELP ENSURE CORRECT SURGERIES

NOTE: *Any special steps taken to ensure a correct surgery, such as the following suggestions, must be recorded in the patient's medical record.*

1. Possible Enhancements to Minimum Pre-Operative Procedures (days to about an hour before surgery)

a. Confirm the site (including laterality if applicable) and the procedure during the telephone call that is typically made to an outpatient 24 to 48 hours before the scheduled procedure.

b. Add to or create a guidebook for patients on what to expect related to their role in ensuring correct surgeries.

c. Standardize a check of the consent form against the Operating Room (OR) schedule 24 hours in advance.

d. Use no abbreviations or acronyms on the consent form or other crucial documents.

e. Do not accept illegible handwriting on the consent form or other crucial documents.

2. Possible Enhancements to Minimum Immediately Pre-Operative Procedures (usually an hour or less before surgery). When asking the patient to verbally state the site, ask the patient to indicate the site by touching it too (as appropriate). This may be especially helpful in cases where disease exists on both sides (e.g., two arthritic knees or two eyes with cataracts), but only one side is scheduled for a procedure on that day.

3. Possible Enhancements to Minimum OR Procedures (minutes to seconds before surgery). Write the patient's name, the location of the site (including laterality), the name of the procedure, and the details of any implants that will be used (e.g., the diopter for an eye implant, the size of femoral head and acetabular component for a hip implant) on a white board or other easily visible place in the OR prior to the start of surgery. Refer to this text in the confirmation process before the start of surgery.